



**USAID** | **TIBA**  
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# FACILITATING ESTABLISHMENT OF A FAVORABLE REGULATORY INFRASTRUCTURE FOR HACCP IMPLEMENTATION BY SMES

## ACTION PLAN

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# 1. Introduction

This action plan was developed as part of the USAID-funded TIBA Project and is ultimately targeted at small and medium-sized enterprises (SMEs) in the Ukrainian food industry with the goal of creating a favorable regulatory environment for implementation of HACCP systems by Ukrainian food processors.

## 2. Goal and Objectives

### *Goal:*

Facilitate better compliance of the Ukrainian agricultural and food industry with SPS requirements.

### *Objectives:*

- Facilitate development of a supportive and favorable regulatory framework for introduction and operation of HACCP systems at food processing facilities in Ukraine.
- Make internationally recognized third-party conformity assessment of HACCP systems (certification) more accessible for domestic food processors, and form domestic teams of specialists.

## 3. Key Issues

The system of ensuring a proper level of control over food safety and timely reactions to emerging challenges that was created to meet the requirements of a centrally planned command economy is outdated and is now being transformed into a new system that works efficiently. Despite numerous efforts and a number of achievements, reforms need to be sped up to meet globally recognized food safety requirements. Ukraine's anticipated accession to the WTO and the need to fulfill requirements of the WTO Agreements on Technical Barriers to Trade (TBT) and on the Application of Sanitary and Phytosanitary Measures (SPS) necessitate continuation and enhancement of harmonization of food laws and practices with international (including EU) requirements, and transparency of procedures for official control over compliance with generally recognized food safety norms and rules in relation both to food produced in and imported into Ukraine.

A globally recognized instrument to ensure food safety is a food safety management system based on HACCP principles. According to the Law of Ukraine "On Amending the Law of Ukraine 'On Quality and Safety of Food and Raw Materials,'" persons who are involved in production or introduction into circulation of food products shall apply sanitary measures and good manufacturing practices, HACCP systems, and/or other systems of safety and quality assurance for production and circulation of food (Article 20, Responsibilities of Producers and Sellers [Suppliers], Par. 6[2]). In addition, since 2003 the National Standard of Ukraine DSTU 4161-2003 "Food Safety Management Systems: Requirements" has been in use. In accordance with WTO requirements, this standard is voluntary. In the near future, this standard should be substituted by the National Standard of Ukraine based on ISO 22000:2005 "**Food safety management systems – Requirements for any organization in the food chain.**" ISO 22000:2005 is an effective and globally recognized tool to prove compliance with food safety norms at a business-to-business level.

Practical experience of TIBA Project staff has shown that in many cases, responsible officials and inspectors have a very limited knowledge of food safety management and HACCP. The information they use is very restrictive, incomprehensive, and not up-to-date; this includes information regarding the latest regulations adopted in other countries or by international organizations that affect the food trade. This makes it difficult for them to perform functions assigned to them by law.

Though approximately 100 food processors have implemented the HACCP system by now, not all of them have had it certified. Of those who have obtained certification, very few enjoy recognition in global markets.

For a quality management system to be internationally recognized, it should be certified by a certification entity that enjoys international accreditation. There are very few entities in Ukraine that are internationally recognized as competent to provide certification (in most cases, they are Ukrainian branch offices of foreign certification authorities) and their services are extremely expensive. This makes it almost unrealistic for SMEs to obtain international certification required by foreign customers. The standards that are mostly used for international certification include ISO 22000:2005, BRC Global Standard – Food, and IFS (International Food Standard). Certification according to these standards is not required by governments of export destination countries; rather, it is a strictly market-driven requirement imposed by buyers.

## 4. Conclusions: General Preconditions and Problems

- 1) Commitments of the Government of Ukraine (as stated in the Constitution of Ukraine and in the Law of Ukraine “On Food Safety and Quality”);
- 2) Global trends that require ensuring uniformity and transparency;
- 3) Ukraine’s international commitments (WTO SPS);
- 4) Aspirations of Ukrainian food processors to explore foreign – including European – markets;
- 5) A lack of common understanding among officials of key basic elements (approaches, conditions, requirements) of food safety throughout the entire food production and processing chain;
- 6) No up-to-date information on the latest trends in the food safety and security area at the policy level; and
- 7) Limited availability of international certification of HACCP systems for SMEs due to high costs and a lack of internationally accredited domestic certification entities.

## 5. Proposed Solutions

Assistance provided by the TIBA Project will focus on creation of a favorable regulatory environment for HACCP implementation among SMEs and include three areas of activity: assisting government authorities involved in HACCP implementation, monitoring, and development of relevant standards; making international HACCP certification more accessible for SMEs; and providing training on HACCP audits.

Food products and food processing chains are very sensitive to two major threats: unintentional contamination during manufacturing and distribution that poses a potential threat to human health (food hazards/food safety), and malicious actions against food supplies (bioterrorism/agroterrorism/food security). Both of these factors present a threat to consumers in countries of origin and destination countries alike, have an extremely negative impact on international trade, and should both be taken seriously by the Government of Ukraine. Capacity-building assistance will be offered to encourage examination of these issues (particularly by the Ministry of Agrarian Policy, Ministry of Health, and State Committee for Technical Regulation and Consumer Policy of Ukraine), including trainings regarding developments in food safety management and bio-security.

Options for international HACCP certification (including in conformance with ISO 22000:2005) will be identified and studied, and recommendations on adoption of certification procedures will be submitted to interested entities; the capacity of domestic entities will be improved to enable them to provide internationally recognized certification to SMEs by raising awareness of consolidated accreditation procedures, offering specific accreditation options, and providing assistance in training auditors.

The domestic entities to be selected as candidates for accreditation should include at least one NGO. A selection procedure will be developed that includes specific criteria for candidate organization activities, areas

of expertise, and history. In general, basic criteria used for international accreditation will apply to selection of candidates in order to make sure that the selected entities are capable of obtaining accreditation.

***These basic criteria will include:***

- Candidate entities must be domestic legal entities; they should not be part of international companies or Ukrainian offices of international certification entities.
- Candidate entities must be
  - Unbiased;
  - Competent;
  - Responsible;
  - Open; and
  - Able to keep information confidential.
- Candidate entities must have qualified personnel.
- Candidate entities must have proven experience in applying HACCP and management systems.
- Candidate entities must commit to following recommendations of TIBA Project experts.
- Candidate entities must commit to collaborating with the TIBA Project in providing SMEs with HACCP assistance at processing facilities.

It should be made clear to the candidate entities that the TIBA Project will not assume financial responsibility and cannot guarantee successful accreditation.

***A pool of trainers*** (a total of 10 persons) will be selected in order to provide auditor training in the future. Progress with international accreditation activities and plant-level HACCP assistance will show what types of auditors (first-party, second-party, or third-party auditors) are most needed. Based on this evaluation, an appropriate training curriculum will be developed. However, training is only one of the requirements for HACCP auditors (along with education and professional background, work experience in conducting audits, etc.); thus, training participants should be made aware of their own responsibilities in meeting all the requirements to be qualified as auditors.

***The trainer candidates shall have the following qualifications:***

- Appropriate educational backgrounds in agriculture, food processing, and food safety;
- Experience in the field of food safety/quality;
- Working knowledge of quality management systems within the relevant manufacturing/processing environment;
- Extensive teaching experience and knowledge of techniques for instructing adults; and
- A commitment to dedicating some of their time to TIBA Project activities and needs.

## 6. Sustainability

These activities will be taken over by domestic entities and continued after the end of the TIBA Project (especially the accreditation aspect) because the demand for international certification will not decrease. Given the export capacity of the Ukrainian food industry, more and more food processors are expected to seek internationally recognized certification to comply with foreign buyers' requirements. Accredited entities will provide fee-based certification services and will be able to cover initial investments that may be needed to achieve compliance with accreditation requirements. HACCP certification services from Ukrainian entities with internationally recognized accreditation can also be requested by processors from neighboring countries because these services are expected to be competitive within the region (no language barrier, lower costs, etc.).

# 7. Action Plan

1. **Create a favorable regulatory environment for HACCP implementation by SMEs** — This activity will be targeted toward filling the critical gap in relevant knowledge between food processors and state officials (assisting the latter with understanding the needs and difficulties of the former) and helping overcome a situation in which the regulatory environment hampers positive trends in industry due to a lack of understanding among officials and an outdated regulatory framework.
  - 1.1 **Assist responsible government authorities in the food safety regulatory area** — This will include facilitation of adoption of globally recognized standards of the ISO 22000 family (in particular, ISO 22000:2005 “**Food safety management systems – Requirements for any organization in the food chain,**” ISO/TS 22004:2005 “**Food safety management systems – Guidance on the application of ISO 22000:2005,**” and ISO 22003 “**Food safety management systems – Requirements for bodies providing audit and certification of food safety management systems**”).
  - 1.2 **Develop awareness and equip state officials with new skills** — Provide trainings on HACCP concepts and international recommendations/standards (Codex Alimentarius, ISO 22000:2005), new developments in food safety management, punishment/motivational instruments to facilitate HACCP introduction (e.g., the “Name and Blame” concept), crisis management, and bio-security (including general concepts, major risks, and prevention/response measures). The trainings will be provided to three key state authorities at least two times and made available to all interested personnel.
2. **Increase availability and accessibility of international certification of food safety management systems for SMEs** — This will be done by preparing three domestic entities (including at least one NGO) for international accreditation as third-party certification bodies; utilizing Ukrainian auditors will help decrease certification costs (by saving on international travel, etc.) and make this process affordable for SMEs.
  - 2.1 **Search for international accreditation bodies and study accreditation requirements and procedures** — This will include compiling a list of international accreditation bodies that offer accreditation for performing food safety management/HACCP certification (including in compliance with ISO 22000:2005), with specific terms and conditions offered by each body and a summary of their requirements in comparative charts to be used by local entities to select the best option. The decision will be made based on demand for a particular certification among domestic SMEs, the most required certifications in target export markets, and rational considerations regarding feasibility of obtaining accreditation from this or that body.
  - 2.2 **Select domestic entities as candidates to apply for international accreditation for HACCP certification activities** — Selection must be thorough and unbiased, and will be conducted based on a set of detailed criteria to be developed (basic criteria are listed in Section 4 above).
  - 2.3 **Develop materials and provide information seminars on accreditation** — Requirements of accreditation standards/procedures used by selected international accreditation bodies shall be translated into guidance materials; trainings will be delivered to management and personnel of selected domestic entities.
  - 2.4 **Provide information to selected domestic entities preparing to apply for international accreditation** — When local entities are preparing to apply for accreditation, they will be provided with recommendations and advice on improvement of internal procedures and practices to bring them into compliance with accreditation requirements; this will be done through visits and face-to-face discussions as well as electronic communication.
3. **Develop a generic training course for HACCP auditors and provide said training to at least 10 persons** — The training materials will be based on experience and reflect requirements of international accreditation bodies to which domestic entities will apply for accreditation. The training will cover *the following general topics*: audit concepts, types of audits, impartiality concepts, auditing skills, communication with clients, complaints and appeals, writing audit reports, reporting audit results to management, etc.